PTO/SB/13 (11-96)
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REQUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60, and/or 37 CFR 1.53(b)

DOCKET NUMBER	ANTICIPATED CLASSIFICATION OF THIS APPLICATION		PRIOR APPLICATION EXAMINER	ART UNIT
	CLASS	SUBCLASS		
4077 DIV REISSUE	—	—	J. SAYDAH	3764

Address to:
Assistant Commissioner for Patents
Washington, D.C. 20231

This is a request for filing a ☐ continuation ☐ divisional application under 37 CFR 1.60, and/or 37 CFR 1.53(b) of pending prior Application Number 08 / 702,107, filed on 8/23/96 entitled PRESSURE APPLICATION METHOD

1. Enclosed is a copy of the latest inventor-signed prior application, including a copy of the oath or declaration showing the original signature or an indication it was signed. I hereby verify that the papers are a true copy of the latest signed prior application number 08 / 702,107, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS (37 CFR 1.16(c))	9 - 20 =	—	x $ 18.00 =	$ —
	INDEPENDENT CLAIMS (37 CFR 1.16(b))	3 - 1 =	2	x $ 78.00 =	156.00
	MULTIPLE DEPENDENT CLAIMS (if applicable) (37 CFR 1.16(d))			+ $ — =	
			BASIC FEE (37 CFR 1.16(a))		+ 760.00
			Total of above Calculations =		916.00
	Reduction by 50% for filing by small entity (Note 37 CFR 1.9, 1.27, 1.28).				—
			TOTAL =		916.00 **

2. ☐ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27
   ☐ is enclosed.
   ☐ was filed in prior application number ____ / _____ and such status is still proper and desired (37 CFR 1.28(a)).
3. ☐ The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. _____. A duplicate copy of this sheet is enclosed.
4. ☒ A check in the amount of $ 916.00 is enclosed.
5. ☐ Cancel in this application original claims _____ of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
6. ☒ The inventor(s) of the invention being claimed in this application is (are): the same as in the identified prior copending application.
7. ☐ This application is being filed by less than all the inventors named in the prior application. In accordance with 37 CFR 1.60(b), the Commissioner is requested to delete the name(s) of the following person or persons who are not inventors of the invention being claimed in this application:
8. ☒ Amend the specification by inserting before the first line the sentence: "This application is a ☒ continuation ☐ division of application number 08/702,107, filed 8/23/96, (status, abandoned, pending, etc.)." CURRENTLY PENDING

[Page 1 of 2]

Burden Hour Statement: This form is estimated to take 0.5 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

**The filing fee includes the fee for the claims presented in the accompanying preliminary amendment.

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(REQUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60, PAGE 2)

9. ☒ New formal drawings are enclosed.

10. ☐ Priority of foreign application number _____, filed on _____ in _____ is claimed under 35 U.S.C. 119(a) - (d).
☐ The certified copy has been filed in prior application number ___/_____, filed _____.

11. ☒ A preliminary amendment is enclosed.

12. ☒ The prior application is assigned of record to RESPIRONICS INC.

13. ☐ Also enclosed:

14. ☒ The power of attorney in the prior application is to: J. STEWART BRAMS

a. ☒ The power of attorney appears in the original papers in the prior application.

b. ☐ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.

c. ☒ Address all future correspondence to: (May only be completed by applicant, or attorney or agent of record.)

☐ Customer Number _____ → *Place Customer Number Bar Code Label here*
OR *Type Customer Number here*

☒ Firm or Individual Name J. STEWART BRAMS
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12-8-99
Date

Signature

J. STEWART BRAMS
Typed or printed name

☐ Inventor(s)
☐ Assignee of complete interest. Certification under 37 CFR 3.73(b) is enclosed.
☒ Attorney or agent of record
☐ Filed under 37 CFR 1.34(a)
Registration number if acting under 37 CFR 1.34(a)._____.

[Page 2 of 2]

J. STEWART BRAMS

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December 08, 1999

Commissioner of Patents & Trademarks
Washington, D.C. 20231

Attn: Assistant Commissioner for Patents

Re: Reissue Patent Application No. 08/702,107
of Mark H. Sanders
filed 8/23/96
for Pressure Application Method
Examiner J. Saydah
Group Art Unit 3764

Dear Sir:

The captioned reissue patent application is pending and awaiting response to the office action mailed 8/31/99. This transmittal constitutes a continuing application filing under 37 CFR 1.60 and/or 37 CFR 1.53(b) to serve as a response to the outstanding action in the captioned case. Enclosed are the following:

- Petition for extension of time under 37 CFR 1.136(a) for response to the outstanding action in the captioned application and express abandonment of the captioned application, including check no. 2073 in the amount of $110 for the requisite time extension fee;

- Original and duplicate of request for refund of the issue fee previously paid in the captioned application;

- Continuing application request and transmittal, including check no. 2072 in the amount of $916 for the filing fee;

- Complete copy of prior copending application SN 08/702,107, including:

  Original Specification and Claims
  Two sheets of formal drawings
  Request for Abstract of Title
  Assignee's Offer to Surrender Original Patent and Assent of Assignee
  Reissue Application Declaration and Power of Attorney by Inventor
  Declaration of Eugene N. Scarberry
  Declaration of J. Stewart Brams;

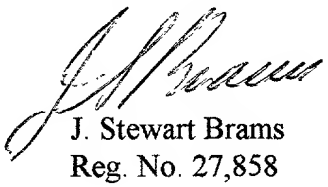
- Preliminary amendment;

- Information disclosure statement.

Applicant notes that various particulars of reissue application processing and prosecution unrelated to issues of claim patentability were dealt with and resolved in the prosecution of the parent reissue application. For example, a request for an abstract of title was filed and the requisite fee paid, and presumably the PTO acted on the request. Additionally, applicant surrendered the original patent to the PTO during prosecution of the parent application. Applicant thus relies on the prosecution history of the parent reissue application as to all such matters of reissue application prosecution to the extent the same were addressed during the prosecution of the parent application.

Please date stamp and return-mail the accompanying postcard to acknowledge receipt of this submittal.

Very truly yours,



J. Stewart Brams
Reg. No. 27,858

JSB/ams
encl.

4077 DIV-REISSUE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reissue Patent Application of	:	
Mark H. Sanders	:	Anticipated Group 3764
Continuation of No. 08/702,107	:	Anticipated Examiner J. Saydah
Serial No. (to be assigned)	:	
Filed (to be assigned)	:	
For Pressure Application method	:	

Pittsburgh, Pennsylvania
December 08, 1999

PRELIMINARY AMENDMENT

Hon. Commissioner of Patents
and Trademarks
Washington, D. C. 20231

Sir:

Please amend the accompanying continuation application as follows prior to any action on the merits.

ON THE PATENT COVER PAGE

Please amend item 75, the identification of the inventor, to read as follows:

[Inventors: Eugene N. Scarberry, Trafford;
Patrick M. Handke, Monroeville;]

Inventor: Mark H. Sanders, Wexford, [all of] Pa.

IN THE SPECIFICATION

Please amend the title of the application to read as follows:

Method of Treating Airway Disorders

IN THE CLAIMS

Please enter claims 4-9 as follows:

4. In the medical treatment of sleep apnea syndrome, the method of treatment comprised of distending frontal portions of a patient's neck in a manner effective for alleviating obstruction of the patient's airway in sleep.

5. The method as set forth in claim 4 including the additional step of simultaneously applying an elevated pressure within the patient's airway.

6. The method as set forth in claim 5 wherein said elevated pressure is of a magnitude greater than ambient atmospheric pressure.

7. In the medical treatment of upper airway disorders, the method of treatment comprised of distending frontal portions of a patient's neck in a manner effective for alleviating obstruction of the patient's airway.

8. The method as set forth in claim 7 including the additional step of simultaneously applying an elevated pressure within the patient's airway.

9. the method as set forth in claim 8 wherein said elevated pressure is of a magnitude greater than ambient atmospheric pressure.

REMARKS

Applicant respectfully requests entry of the above amendments in the accompanying continuation application prior to any action on the merits.

These amendments are intended to conform the accompanying continuation application to prior copending reissue application Serial No. 08/702,107 as currently pending, and in addition to incorporate the unentered Amendment under Rule 116 which was filed in the identified prior copending application on October 8, 1999.

In order to comply with various requirements for reissue application amendments stated at MPEP 1453, applicant notes the following:

- The status of all claims is as follows. Claims 1-9 are pending
- The above amendments add claims 4-9, which claim the invention without reference to pressure less than ambient as a preferred impetus for distending frontal portions of a patient's neck.
- Support for claims 4-9 is found in the patent specification at, inter alia, Col. 6, Lines 34-40, and Col. 9, Lines 17-20 and 28-36.

Applicant notes that in the identified parent application the question of correct inventor identification has been addressed and resolved, but the amendment is presented again here as the accompanying continuation application is not being filed under any "continuing prosecution" procedure. For this and all other aspects of reissue application prosecution, excepting only prosecution of added claims 4-9, applicant relies on and hereby incorporates by reference the prosecution history of parent application Serial No. 08/802,107.

The above claim amendments address the rejection under 35 USC 112 of record in the parent application, in which examiner held the recital of an "impetus" is new matter. The above claims 4-9 overcome the Section 112 rejection by reciting the novel method in terms of distending action applied to frontal portions of a patient's neck, without reference to an impetus. The claims thus are more consistent with the disclosure of the original specification. Claims 4-9 also are believed to distinguish patentably over all art of record.

Applicant has previously traversed the new matter rejection in the parent application. Substitution of "impetus" for the original "pressure sufficiently less than ambient pressure to distend..." is not new matter. Surely examiner will concur that the claims as now presented find support in the original specification and contain no new matter. The specification clearly discloses the action of distending frontal portions of a patient's neck. Yet examiner is also of record as holding, with respect to the unamended version of the same claims, as originally presented in the parent application, that the "specification, as originally filed, does not provide support for the breadth of the invention as is now claimed" (parent application, office action 6/18/97). How can it be that the

claims reciting an "impetus" (rather than a pressure as in the issued patent claims) find no support in the specification, while the broader amended claims presented above, which recite neither impetus nor pressure, are supported by the specification?

The answer is that the narrower claims reciting an impetus indeed are supported by the specification, because a disclosure of method in terms of action steps always implicitly includes an impetus to drive the disclosed action. Even though an impetus is not recited in newly presented claims 4-9, the argument is not moot. The point to be made is that the patentable method requires no impetus limitation at all, whether a general or a specific one, because the patentable method is the action, not the impetus that drives the action. This is commonplace in claim construction. Patentable method claims routinely recite action steps without reference to the impetus that drives the action. Applicant thus submits that claims 4-9, either with or without recital of an impetus, include no new matter and are fully supported by the original specification .

Applicant respectfully requests entry of the above amendments prior to any action on the merits, consideration of the above remarks, and notice of allowance as to all pending claims.

Respectfully submitted,

J. Stewart Brams
Agent for Sanders

JSB:ams
Reg. No. 27,858
(412) 831-7430

PRESSURE APPLICATION METHOD

BACKGROUND OF THE INVENTION

This is a division of application Ser. No. 07/895,225, filed Jun. 8, 1992, now U.S. Pat. No. 5,222,478.

In the art of respirators, resuscitators, and the like it is well known to provide apparatus in the form of an enclosure which encompasses a portion of the human body such as the upper torso or thoratic region thereof to provide within the confines of the enclosure a pressure containment chamber wherein pressure variations may be applied to the body to stimulate respiration. A wide variety of such devices are known, the following prior art being representative.

U.S. Pat. No. 3,078,842 discloses a resuscitation apparatus which employs a rigid shell to enclose the torso of a human body. U.S. Pat. No. 4,523,579 discloses another rigid shell type body respirator having flexible side walls. U.S. Pat. No. 2,241,444 discloses a respirator jacket comprised of a rigid shell made by laying up reinforced plaster of paris material on a plaster cast which has been molded to the body contours of the individual user, and which includes an enlarged cavity confronting the chest and adjacent abdominal region of the user. Other rigid shell type resuscitators are disclosed by U.S. Pat. Nos. 4,257,407 and 2,309,361. The latter of these discloses a padded liner in a rigid generally form-fitting respirator.

U.S. Pat. No. 2,899,955 discloses a respirator belt which encircles the waist of a user and includes an inflatable bladder to which air pressure is directed for assisted breathing. U.S. Pat. No. 4,621,621 discloses a respirator including a rigid wire cage that encompasses a portion of a user's body and is in turn encompassed by an air tight cover to provide a vacuum chamber surrounding the user's body. U.S. Pat. No. 3,577,977 discloses a flexible, inflatable bladder-type jacket and U.S. Pat. No. 2,480,980 discloses a rigid, generally form-fitting respirator jacket. Finally, U.S. Pat. No. 4,664,098 discloses a cardio-pulmonary resuscitator which is worn by a patient in the manner of a belt encompassing the abdominal region.

Notwithstanding such known devices, practitioners in the art have continued to seek improved body respirators. For example, improvements have been continually sought in body respirator compactness, portability, user comfort, reduced power requirements, and of course improved therapeutic efficacy.

Also known in the prior art are a variety of vacuum devices for immobilizing a part of a body. The Rapid Form TM brand vacuum splint is one example. Such devices utilize a structure known as vacuum beads to provide a selectively rigid or flexible member that is used, for example as in the case of the above specified vacuum splint, to immobilize selected body parts that have sustained bone fractures or the like. Such known devices generally comprise a thin section airtight envelope filled with material such as styrofoam beads which interengage and deform upon application of a vacuum within the envelope to thereby render the vacuum bead material relatively rigid. The rigid vacuum bead material thus is utilized to immobilize a selected body part.

BRIEF SUMMARY OF THE INVENTION

The present invention contemplates a novel and improved body respirator, resuscitator, pressure or pulse monitoring apparatus or similar apparatus such as a

wrap or sheath, or a breathing mask which is universal in its application by virtue of its being very closely form-fitting for any selected user irrespective of variations in body size or contours from one user to another. The invention also is light in weight and compact, imposes minimal power requirements for its use, and provides greatly enhanced user comfort and therefore enhanced user tolerance. The invention thus provides greatly enhanced convenience for the user as well as for emergency rescue teams and others who may encounter the need for regular access to emergency equipment of this sort, among other advantages. The invention also contemplates a novel and improved method for the use of varying pressures in a variety of medical applications.

The apparatus of this invention contemplates, in one of several presently preferred embodiments, a body enclosure comprised of a sheath or wrap of selectively flexible or rigid material, such as the above characterized vacuum bead structure or the like, formed to encompass a selected body portion and including seals to seal perimeteral portions or other portions of the body sheath, for example to seal about the openings through which adjacent body portions project such as at the waist, neck, or arms.

The sheath is adapted to be placed in closely spaced form-fitting relation encompassing a portion of the user's body to define, in a zone between the sheath and the user's body, a very thin-section chamber or space The sheath is then selectively rigidified, as by application of a vacuum if comprised of conventional vacuum bead material, to form a rigid, form-fitting enclosure about the encompassed portion of the patient's body whereby the chamber or space between the sheath and the user's body is provided with a rigid outer wall which closely conforms to the adjacent body contours of the user. Pressure or vacuum generating equipment may be utilized to apply pressure variations within this space to act on the flexible inner wall (i.e. the user's body) to assist user ventilation or for other purposes. Alternatively, the pressure within the space may be observed to monitor user pulse, breathing, or the like.

Because the sheath is selectively rendered rigid or flexible, it is quite compact and easily stored when not in use. Because it is placed about the user's body in a flexible state, it is universal in application and extremely closely form fitting with the attendant benefit that the containment space defined between the sheath and the user's body is of minimal volume. Effective operation thus is achieved with minimal power requirements and minimal required compressor or vacuum pump delivery rates.

The invention additionally contemplates spacer means disposed within the pressure containment space between the sheath and the user's body so as to define a predetermined minimal spacing therebetween so that the form and volume of the pressure containment space may be readily controlled. The spacer means is of a structure (e.g. open cell foam) to permit pressure variations introduced at one point within the containment space to be transmitted throughout the space even if the spacer means is substantially co-extensive with the pressure containment space.

The invention additionally contemplates a novel and improved method of pressure utilization in conjunction with the body of a user with advantages corresponding to the above noted and other advantages of the novel apparatus.

It is accordingly one object of the invention to provide a novel and improved body respirator, resuscitator, or the like.

It is a further object of the invention to provide an improved apparatus and method for the utilization of external pressure in the medical treatment of a patient.

A more specific object of the invention is to provide a selectively rigid, flexible body wrap, sheath, mask, vest, or similar apparatus which is adapted to encompass a portion of a body to thereby define in conjunction therewith a sealed space adjacent the body such that pressure controlling or monitoring means cooperable with the sheath is operable to selectively vary or monitor the pressure within the sealed space.

These and other objects and further advantages of the invention will be more readily understood upon consideration of the following detailed description and the accompanying drawings, in which:

FIG. 1 is a frontal elevation of one presently preferred embodiment of the instant invention;

FIG. 2 is a side elevation, partially broken away to show details of an alternative embodiment of the invention shown encompassing the body of a user;

FIG. 3 is an enlarged detailed portion of FIG. 2 including schematic representation of a vacuum pump and pressure controller according to one presently preferred embodiment of the invention;

FIG. 4 is a perspective view of a wrap or sheath apparatus according to an alternative embodiment of the invention; and

FIG. 5 is a sectioned side elevation of a breathing mask or similar apparatus according to another alternative embodiment of the invention.

There is generally indicated at 10 in FIG. 1 a body respirator or the like constructed according to one presently preferred embodiment of the invention and including a body sheath 12 formed for purposes of this embodiment as a vest or jacket and including, when enclosed about the user's body, a neck opening 14 as well as arm holes or apertures 16.

Suitable fasteners are provided, for example Velcro TM or similar interengaging tapes, to maintain a front opening 18 tightly closed and sealed when the vest is donned and in use, and to thus maintain the sheath 12 in closely form-fitting relation about the upper torso or thoratic region of the user's body.

An alternative form of the sheath or vest as identified at 12' in FIG. 2 passes beneath the arms of the user so no arm holes are required. The sheath 12' encompasses the user's waist and upper chest. For the embodiments shown in FIGS. 1 and 2, all openings from which parts of the user's body project are sealed by suitable seal means such as encompassing band means 20 to form intermediate the sheath and the body 22 (FIG. 2) of the user a sealed space or chamber 32.

Other differences of the FIG. 2 embodiments from that of FIG. 1 include buckle and strap fasteners 24 in lieu of fasteners 17 and the location of closure 26 of adjacent one side of the user's body rather than extending vertically along user's front as does opening 18 of the FIG. 1 embodiment. Of course, a wide variety of alternative configurations may be utilized in accordance with the specific purposes and desired features of the sheath 12. Specifically, an apparatus according to this invention but adapted to encompass a body part other than the chest or abdominal region will of course be configured accordingly.

Regarding further aspects of the invention, as exemplified by FIG. 2, sheath 12' comprises a selectively rigid or flexible wall system 28 which is maintained in closely spaced relationship with respect to the user's body 22 as by means of spacers 30, which may be of such suitable structure as open cell foam to permit the transmission of pressure variations imposed at one location within the confines of the sheath 12' to all locations therein.

The spacers 30 may occupy only a small portion or alternatively substantially all of the volume of the space 32 defined intermediate sheath 12' and the user's body 22, within the confines of perimeteral seals 20. It will be noted, however, that space 32 need not be coextensive with the mutually contiguous zones of sheath 12' and the user's body 22, that spacers 30 may be of other suitable structure or may be eliminated entirely, and that seals 20 need not be disposed about perimeteral portions of the sheath 12' where portions of the user's body extend therefrom.

The invention thus contemplates an apparatus which is utilized to form a sealed space between a body sheath and a user's body with the sealed space being defined generally by an inner wall system comprised of a portion of the user's body, an outer wall system comprised of a corresponding adjacent portion of a sheath wall disposed in closely spaced form-fitting relation with respect to the user's body. A seal system seals all interfaces between the sheath and the user's body that are exposed to pressure variations introduced within the sealed space.

It is noted that seals are to be provided to seal any opening which is provided to facilitate installation or removal of the sheath, for example opening 18 of FIG. 1 or 26 of FIG. 2. These and any other such openings would require seals to preclude leakage due to a pressure differential between ambient and the pressure condition within space 32.

There is shown in FIG. 3 a portion of the novel body respirator. In FIG. 3, sheath 12' is comprised of an outer flexible shell 34 of sheet polyethylene for example, which is coextensive with the selectively rigidified structure 36. Structure 36 comprises a pair of flexible, closely spaced, air impermeable inner and outer walls 38 and 40 of such suitable material as vinyl or polyeurethane impregnated nylon. The inner and outer walls 38 and 40 are sealed together along a continuous line encompassing a space 42 therebetween, which space 42 contains a mass of interengageable elements 44 such as beads of styrofoam brand plastic. Air permeable partition elements 41 joined to and extending between walls 40 and 38 may be provided at intervals in space 42 as barriers to prevent undesirable migration of beads 44 within the space 42.

As is known, the above described structure is typical of vacuum bead type systems wherein the application of a vacuum within space 42, as by means of a vacuum pump 46, causes walls 40 and 38 to collapse inwardly under the impetus of external ambient air pressure against the beads 44. Thus, upon imposition of such a vacuum in space 42, the styrofoam beads 44 deform in interengagement and lock up in an immobilized state to form a rigid shell from the previously flexible shell. Upon release of the vacuum drawn within space 42, the styrofoam beads 44 are released from their mutual interengagement and the vacuum bead structure 36 becomes once again flexible.

Carried adjacent the inner wall 40, and preferably affixed thereto in a suitable manner is the spacing material 32 as above characterized. In use, the innermost extent of the spacing material 32 engages the body of the user 22 to thereby establish and maintain a generally uniform spacing or separation between the sheath 12' and the user's body 22.

Of course, the spacing therebetween is uniform only if the spacer element 32 is of uniform thickness. More generally, the spacing between sheath 12' and user's body 22 may vary according to variation in the thickness of the spacing elements 32. Also, and as noted hereinabove, the spacing element 32 may be omitted entirely as it is contemplated that only a very thin section space generally is necessary between the user's body and the sheath 12' for effective operation of the invention.

As further shown in FIG. 3, the invention additionally comprises a pressure controller 48 which is powered by any suitable and conventional power means to deliver air flow under pressure to space 32 in order to impose within space 32 controlled pressure at variance with ambient atmospheric pressure. For example, pressure controller 48 may be utilized to impose alternating or cyclic elevated pressure within space 32, or a partial vacuum.

In order to accommodate the pressure controller 48, a suitable air flow delivery conduit 50 provides an air flow path between pressure controller 48 and space 32, and of course therefore traverses the sheath 12'. In a preferred embodiment the sheath 12' will include a port means having any suitable, known coupling 51 or air conduit connection on the outer side thereof for connection to a delivery conduit from pressure controller 48

For emphasis it is reiterated here that the apparatus of this invention may take any of a variety of forms to encompass any portion of a user's body other than the chest or thoratic region and for a variety of purposes other than respiratory assistance. For example, an apparatus similar in many salient respects to that above described and encompassing the thoratic region may be utilized with alternating pressure, and in conjunction with alternating pressure delivered in a specified phased relationship to the airway of a patient to function as a heart pump for cardio-vascular resuscitation. In another alternative mode of use, the apparatus of this invention may be utilized with pressure monitoring equipment 49 (FIG. 3) which is connected via a conduit 53 to space 32 for the purpose of monitoring pressure therein. Thus any physical response of a user which causes variation of the pressure within space 32, pluse or spontaneous breathing for example, may be observed by use of pressure monitor 49.

The invention may also be embodied as a wrap or sheath as above mentioned, for example a wrap or sheath for a limb or other extremity. FIG. 4 shows such a wrap or sheath 60 which is adapted to encompass a human limb or any similarly configured body part, for example, the neck. The sheath 60 is comprised of an elongated flexible band 62 which forms an elongated, thin section envelope 64 that contains therein material such as styrofoam beads similar in all salient respects to the above described vacuum bead structures. Fastener bands 66 are affixed adjacent one longitudinal end of band 64 as by stitching 68 and cooperating fastener strips 70 are similarly affixed adjacent the opposed end of band 62. Fastener strip 66 and 70 may be cooperating

hook and loop type fastener strips such as Velcro TM brand fastener material.

Sheath 60 may also include seal means such as a patch seal 72 in the form of a foam rubber or similar sealing strip affixed to one side of band 62 intermediate its longitudinal ends and forming thereon a closed perimeter which defines within its confines a space 74. A suitable vacuum connection 76 communicates with space 74, for example by penetrating the band 62 via a fitting 78 within the confines of seal 72. The sheath 60 thus may be applied to a human limb or similarly configured body part as a wrap with the fastener strips 66 and 70 overlapping to maintain the band 62 in encompassing relationship on such a body part and with an outer seal surface 80 of seal member 72 engaging a corresponding surface portion of such body part continuously along the extent of seal 72. By application of vacuum as via a vacuum connection 82, the band 62 may be selectively rigidified in encompassing relationship about a human limb as described. In an alternative embodiment, the selectively rigidified part of band 62 may be limited to that part encompassed by seal 72.

For either embodiment, the application of vacuum to the band 62 as described forms a relatively rigid outer wall for space 74 with the inner wall thereof being that portion of the patient's body encompassed by seal 72. Accordingly, pressures varying from ambient atmospheric pressure may be applied for therapeutic effect to that portion of the patient's body exposed to such pressure variation within the confines of seal 72 in much the same manner as pressure variations are applied to the upper thoracic region as above described with reference to FIGS. 1 through 3.

Specifically, since the outer wall of space 74 is rigid, the application of elevated pressure above ambient pressure via connection 76 in space 74 will tend to compress the corresponding adjacent portion of the patient's body which forms the inner wall of space 74 whereas a partial vacuum within space 74 will tend to distend the adjacent body portion by drawing it into the space 74.

Another alternative embodiment of the invention is shown in FIG. 5 as a breathing mask 83 having a generally rigid body 84 which carries a seal assembly 86 that encompasses an open space 88 which communicates through body 84 with a gas supply connection portion 90 of mask body 84. Accordingly, mask 83 may be placed with seal assembly 86 in confronting engagement with a user's face so that seal assembly 86 encompasses the nose or the nose and mouth of a user. Breathing gas for the user is then supplied exclusively through connection 90.

Since the function of a breathing mask such as shown in FIG. 5 differs from the function of a body type respirator such as shown in FIGS. 1 through 3, the expanse of space within the confines of seal 86 need not be enclosed by the vacuum bead material to provide a rigid outer wall such as is required for the respirator of FIGS. 1 through 3. Rather, for the FIG. 5 embodiment of the invention, the function of vacuum bead structure as described hereinbelow is to provide an effective and and closely conforming surface seal to fit a wide variety of user facial contours in more or less universal fashion whereby a single mask may be readily adapted for use by virtually any patient.

Accordingly, it will be seen that seal assembly 86 comprises a flexible perimeteral wall system 92 comprised of rubber for example, and formed in a closed ring with a generally tubular cross section. The space 94

closed within the wall system 92 is filled preferably with vacuum bead material such as above described with reference to FIGS. 1 through 3, for example styrofoam plastic beads.

The resilient wall element 92 is mounted upon mask body member 84 and extends outwardly therefrom, and a seal member 96 may be affixed to an outer extent of wall element 92 for confronting sealing engagement with a user's face. A vacuum connection 98 is provided to permit drawing a partial vacuum upon space 94 with seal 96 in engagement with that portion of a user's face encompassing the nose or the nose and mouth. The partial vacuum, acting on the mass of interengageable beads, causes them to become forcefully interengaged under the impetus of ambient atmospheric pressure compressing the flexible wall element 92 inwardly. The mass of beads thus becomes rigid and supports the wall 92 against inward collapse. The wall 92 thus holds whatever form it and the contained beads have assumed by virtue of sealing pressure against the face of a user. Accordingly, the mask 83 is effective universally for any user as the seal thereon readily conforms, and is maintained in conforming relationship to the user's face by virtue of operation of the vacuum bead apparatus as described

For purposes of this invention, including all embodiments described hereinabove, the structure of the vacuum bead material may include a variety of alternatives including styrofoam beads as above described or alternatively a finely divided powder with similar mechanical properties. Additionally, the material within the vacuum envelope may be infused or coated with a bonding agent such as a heat curing adhesive to permit the set or shape of the vacuum bead structure, once established by the vacuum action, to be permanently maintained. This is done by subjecting the vacuum bead material to sufficient activating or curing energy such as heat for curing a heat cured adhesive. Other types of bonding systems may also be used, for example chemical curing systems, pressure sensitive adhesives, photosensitive or light curing systems, and so forth. Any adhesive will suffice which provides the function of maintaining the shape or form of the vacuum bead structure after release of the vacuum by bonding the individual vacuum beads or similar elements together. Some adhesive systems, such as heat curing or heat setting adhesives, would for all practical purposes be limited to use in a structure as described which is to be permanently maintained in the form suited to a particular user. That is, once the heat setting adhesive is cured, it would not be possible re-use the same adhesive. By contrast, a hot melt adhesive or similar bonding system would permit re-use of a mask or respirator structure according to this invention for another user as the bonds between interengaged vacuum beads could be broken by mechanical force (i.e. massaging or kneading the vacuum bead envelope). The mask or respirator could then be fitted to a different user, the vacuum applied to maintain the resulting seal and/or space configuration, and the vacuum bead material then once again subjected to heat to melt the adhesive and bond the vacuum bead materials in the new configuration.

The seal 96 of FIG. 5 or corresponding seal elements from other disclosed embodiments similarly may take a variety of forms including a rubber surface seal as shown, or alternatively an inflated bladder seal filled with air, foam or gel, a flap seal, or the like. Any of these may include a tacky outer surface for engagement

with the respective body part of a user to provide sealing with a user's body in part by temporary, releasable adhesion to the skin. Another seal structure contemplated includes a closed envelope containing a hydroscopic gel material which has cushioning properties and a tacky character such that the seal is resilient at low mechanical loads but is permanently deformed by larger loads. The air filled bladder seal generally may be a tubular bladder with air space encircling a space similar to 94 that contains therein vacuum bead material or any alternative as above discussed. In addition, it is contemplated that the outer surface of wall 92 may function itself as a seal for confronting engagement with a body portion of a user such that a separate seal member such as at 96 in FIG. 5 may be entirely eliminated.

In an additional alternative embodiment applicable to any of the above described structures, the invention may be comprised of a body member which carries a separate, replaceable vacuum bead liner structure as opposed to having the vacuum bead structure permanently installed with other elements of the invention.

One advantage of the mask structure of FIG 5 is that when vacuum is applied via connection 98, the vacuum bead material 95 will be maintained in a rigid form defining an outer profile for sealing in close conformity to the face of a user; however, if leaks should be present in such a seal, the vacuum bead material 95, even when under vacuum, can be formed or molded by the application of mechanical pressure (i.e. finger pressure) to change the seal profile or configuration. Accordingly, if leaks are detected after application of vacuum, the medical practitioner can eliminate such leaks with mere finger pressure applied against wall element 92 adjacent the leak. Such mechanical pressure will displace the wall 92 inwardly thus moving or displacing the immediately adjacent vacuum beads. Since under such relatively small and non-uniform mechanical pressures the individual beads are not significantly compressed but merely redistributed, mechanical finger pressure as described will force some of the vacuum bead material outwardly in the direction of seal 96 to thereby close the leak. Thus, with the combination of direct fitting to the face of the user, application of vacuum to maintain resulting shape, application of mechanical pressure as needed to effect proper seal conformity with the user's face, and finally application of heat or other mechanism to set an adhesive supplied within space 94 to the vacuum bead material 95, the mask 83 provides for a custom fit to any user, which custom fit is then maintained indefinitely for as long as that user must use the mask The same mask may then be reused to fit any other user with a similar custom fit to provide seal integrity of equal quality.

In still another alternative embodiment of the invention, the vacuum bead material 95 may be supplanted entirely by a heat cure or similar adhesive in powder, granular or bead-like form. Although such a structure is believed to be less useful for repeated universal applications, it would be the equal of other above described embodiments for providing a closely conforming seal in a single use for any user irrespective of differences in facial contours.

Entirely similar structural alternatives as above disclosed also are contemplated for the embodiments of FIGS. 1 through 4 inclusive, and for still further embodiments not heretofore discussed, For example, the disclosed mask structure also contemplates such alternatives as a mask effectively functioning as a perme-

teral seal with nasal cannulae protruding within space 88 to be received into the nares of a user.

From the above description, the novel method will also be apparent as including, inter alia, the steps of encompassing or enclosing a patient's body portion with a flexible structure including a seal to provide sealing against selected body portions to form a chamber or enclosed space, and rigidifying at least a part of the structure to provide a rigid boundary for a corresponding part of the enclosed space. Then one may selectively vary the pressure condition within the enclosed space from ambient either at will or in a predetermined program of pressure variation, or by voluntary or involuntary patient response, and as a further optional step, such pressure variation occurring within the enclosed space may be monitored.

According to another aspect of our novel method, the encompassing of a patient's body portion with a flexible sheath as hereinabove specified may be performed as a treatment for obstructive sleep apnea. Sleep apnea is a widespread sleep disorder estimated to affect up to 3% or more of the general population and commonly characterized by occlusion or obstruction of the upper airway in sleep with resultant disruption of breathing and sleep patterns. The condition carries potential serious consequences including oxygen starvation.

The method of the invention accordingly contemplates the application of negative pressure (i.e. pressure below ambient atmospheric) at least to frontal areas of a patient's neck to thereby draw out or distend the adjacent tissue thus permitting the relatively elevated ambient pressure in the airway, or artificially elevated pressure therein such as CPAP (continuous positive airway pressure), to expand or distend the upper airway thereby relieving the airway obstruction.

According to the description hereinabove there is provided by the instant invention a novel and improved method and apparatus for the external application of pressure variations to a portion of a user's body. The invention may be utilized to apply pressure at decreased or elevated magnitude with respect to ambient, or in a program of varying pressure magnitudes applied by

automatic or manual control, or even pressure variations from ambient or from elevated or decreased pressure magnitudes resulting from voluntary or involuntary user response. The invention further contemplates the monitoring of any such pressure magnitude or variation thereof.

Respecting the FIG. 1 through 3 embodiments, the invention also contemplates an apparatus comprised of separate inner garment, vacuum bead shell, and outer garment structures. The inner garment may be, for example, a foam rubber shell bonded to a fabric backing for the purpose of separating the vacuum bead structure from the user's body. The outer garment may be of the character above described with reference to flexible shell 34, and may include all of the requisite seals such as the described seals 20. Thus it will be clear that the above described components of the invention may be integrally formed together, formed separately and permanently or separably connected, or formed separately and applied one over the other to make up a flexible body enclosing sheath apparatus as above described.

As the inventors herein, we have contemplated these and other alternative and modified embodiments, and certainly such would also occur to others versed in the art once they were apprised of the invention. Accordingly, it is intended that the invention be construed broadly and limited only by the scope of the claims appended hereto.

We claim:

1. In the medical treatment of sleep apnea syndrome, the method of treatment comprised of applying to frontal portions of a patient's neck a pressure sufficiently less than ambient pressure to distend adjacent neck tissue in a manner effective for alleviating obstruction of the patient's airway in sleep.

2. The method as set forth in claim 1 including the additional step of simultaneously applying an elevated pressure greater than the first mentioned said pressure within the patient's airway.

3. The method as set forth in claim 2 wherein said elevated pressure is of a magnitude greater than ambient atmospheric pressure.

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FOREIGN PATENT DOCUMENTS

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Primary Examiner—Richard J. Apley
Assistant Examiner—Linda C. M. Dvorak
Attorney, Agent, or Firm—J. Stewart Brams

[57] ABSTRACT

A method of treating sleep apnea by the novel application of pressure varying from ambient pressure to external portions of a patient's neck, and a novel breathing mask seal apparatus.

3 Claims, 2 Drawing Sheets

FIG. 1

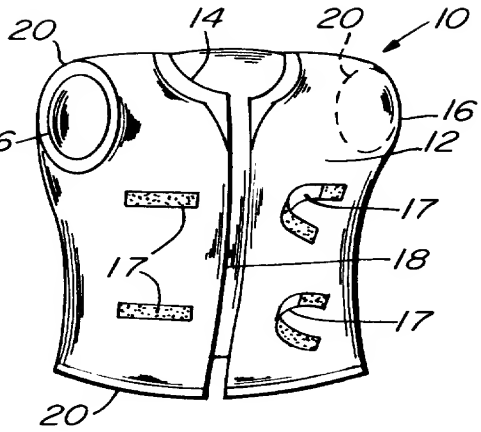


FIG. 2

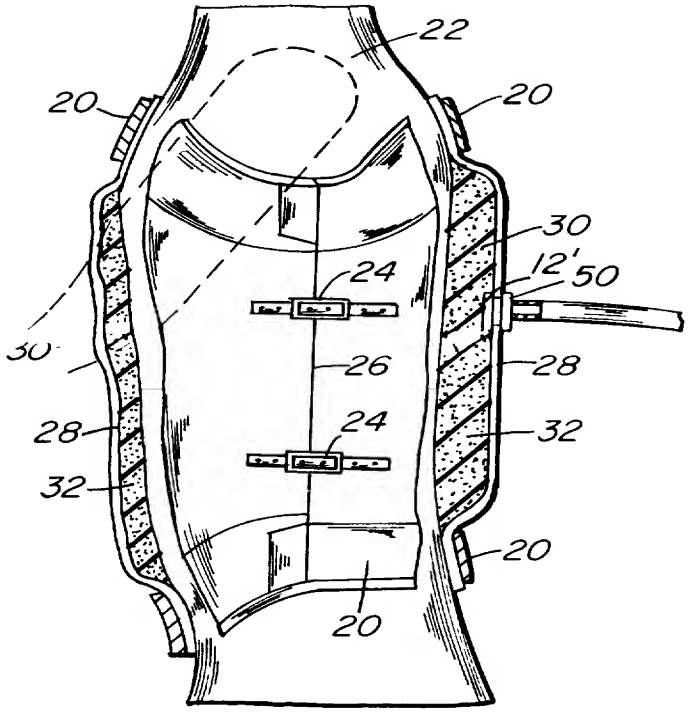


FIG. 3

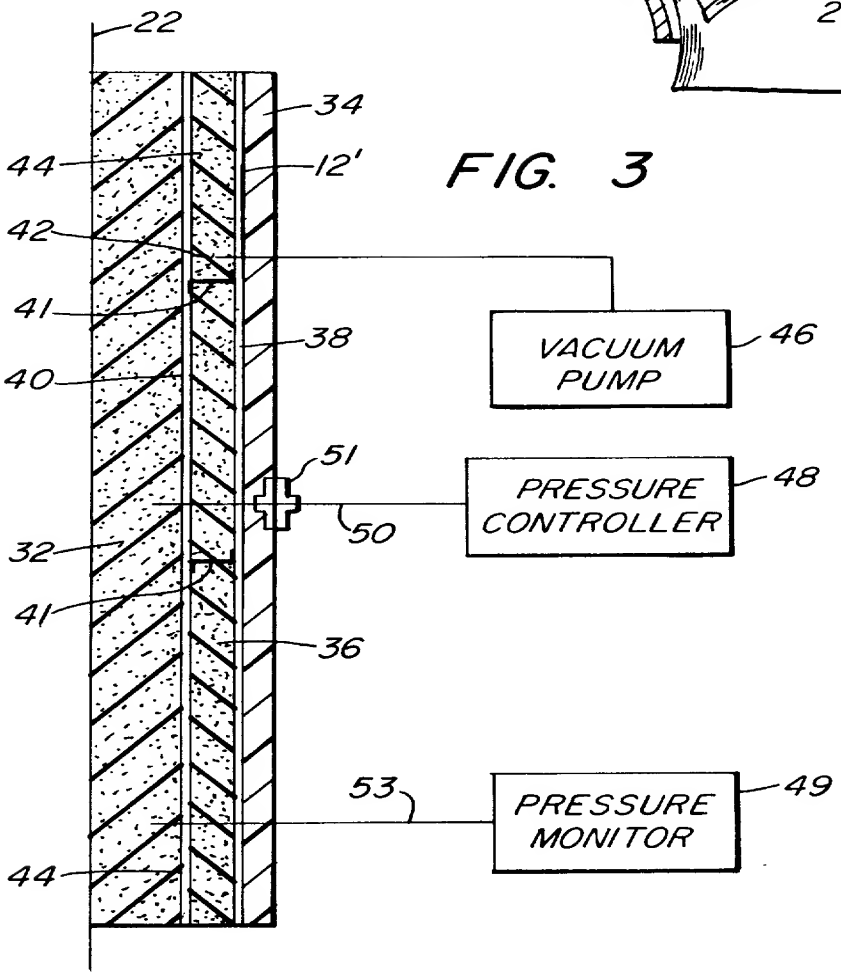


FIG. 4

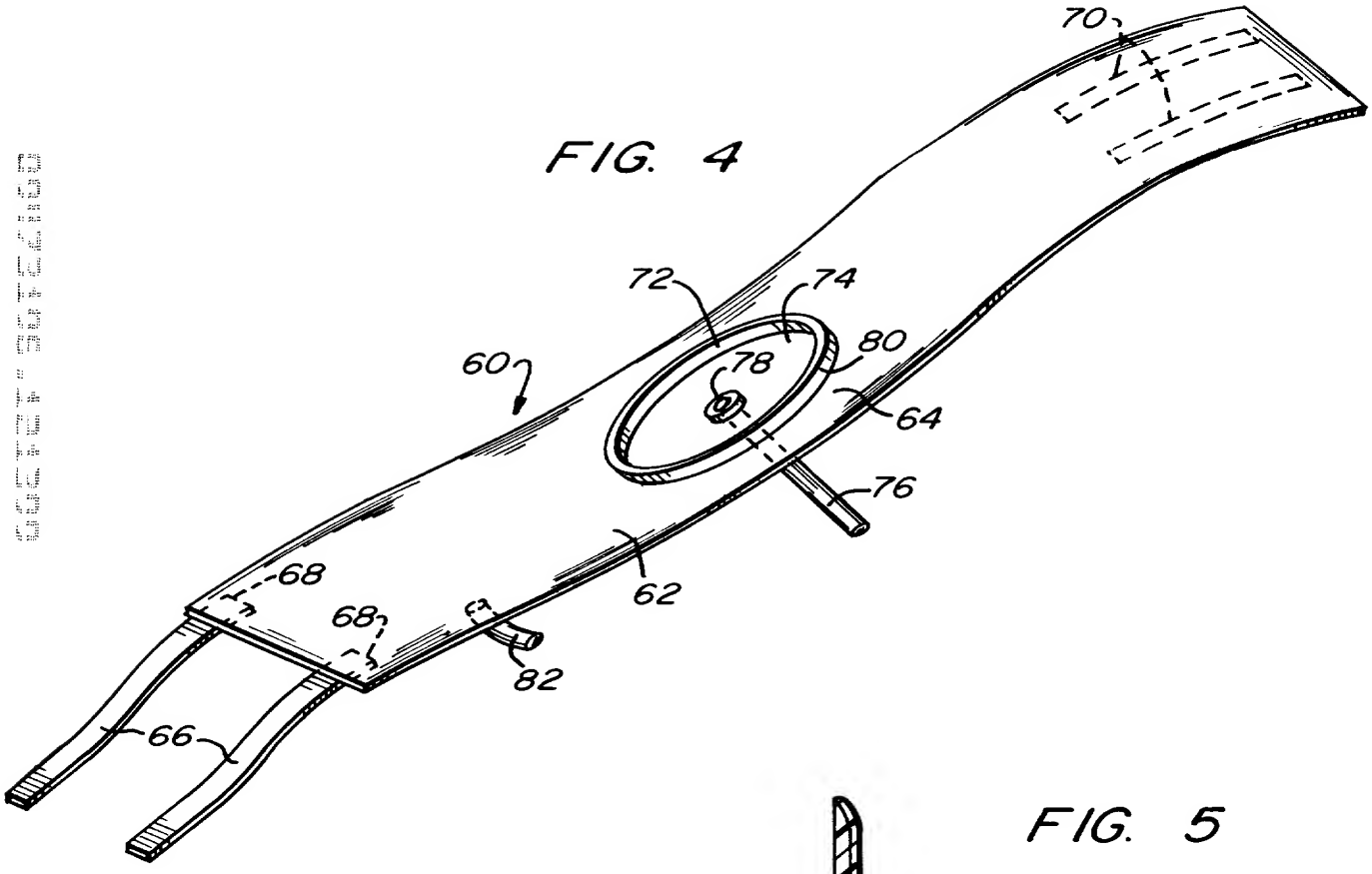
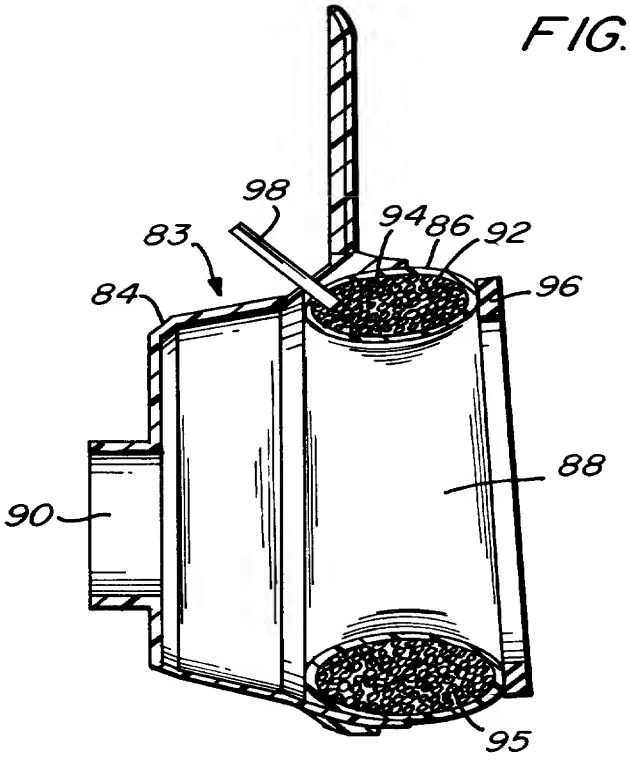


FIG. 5



4077 DIV-REISSUE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reissue Patent Application of	:	
Mark H. Sanders	:	
Serial No. (To be assigned)	:	Examiner (to be assigned)
Filed (To be assigned)	:	Group (to be assigned)
For Reissue of Patent 5,343,878	:	
Issued September 6, 1994	:	
For Pressure Application Method	:	

Pittsburgh, Pennsylvania

Jul 22, 1996

REISSUE APPLICATION DECLARATION AND

POWER OF ATTORNEY BY INVENTOR

Hon. Commissioner of Patents

and Trademarks

Washington, D. C. 20231

Sir:

I, Mark H. Sanders, hereby declare that:

1. I am a citizen of United States of America and a resident of Wexford, Pennsylvania, that my residence and post office address is as indicated below next to my signature, that I believe I am the original, first and sole inventor of the subject matter described and claimed in U. S. Patent 5,343,878 and in the foregoing specification, and for which invention I hereby solicit a reissue patent.

2. I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by the accompanying Preliminary Amendment.

3. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with 37 CFR 1.56.

4. I believe patent 5,343,878 to be partly inoperative because of error which occurred without any deceptive intention, by reason of my having claimed less than I had a right to claim, and by reason of the U.S. Patent & Trademark Office having erroneously identified the inventive entity on the face of the patent.

5. Specifically, claims 1 to 3 of patent 5,343,878 are directed to a method of treating sleep apnea syndrome, and recite, inter alia, applying to frontal portions of a patient's neck a pressure sufficiently less than ambient pressure to distend adjacent neck tissue in a manner effective for alleviating obstruction of the patient's airway in sleep. Directing the claims to treatment of sleep apnea syndrome improperly limits the claims in that the pertinent disclosure in the patent is not limited to treatment of sleep apnea syndrome. Likewise, the recital of pressure less than ambient pressure to distend neck tissue improperly limits the claims because pressure less than ambient pressure was merely my preferred modality for applying an impetus to distend the patient's neck tissue.

6. On reviewing the specification of patent 5,343,878 it is clear to me that I broadly disclosed, at column 9, lines 28 to 36 for example, a method of treatment, not limited to sleep apnea syndrome treatment, which includes

applying to frontal portions of a patient's neck an impetus which distends adjacent neck tissue. Thus, through error I claimed less than I had a right to claim in the patent.

7. As to the further error in identification of the inventorship on the face of patent 5,343,878, I am sole inventor of the invention claimed in the patent, the additional named inventors Scarberry and Handke having been erroneously included on the face of the patent.

8. The prosecution of patent 5,343,878 was conducted by the assignee of record, Respironics Inc., through the agent of record, J. Stewart Brams. I therefore have no personal knowledge of how the above specified errors occurred or were discovered; however, I have read the supporting declarations of Eugene N. Scarberry and J. Stewart Brams, copies of which are attached hereto as Attachment A, and I believe they accurately set forth the circumstances of how the specified errors occurred and were discovered.

9. Until so advised by a letter from J. Stewart Brams dated June 21, 1996, and during a meeting with Mr. Brams on July 2, 1996, I did not know or appreciate that the application disclosed, and that I could claim, a method for treating sleep apnea syndrome, or more generally a method for treating an upper airway disorder, which included applying to frontal portions of a patient's neck an impetus supplied by a suitable modality to distend adjacent neck tissue in a manner effective for alleviating obstruction of the patient's airway in sleep. I now understand that limitation of the patent claims to treatment of sleep apnea syndrome, and to the specific modality of pressure less than ambient pressure to provide the distending impetus resulted in the

patent claiming less than I had a right to claim.

10. I hereby appoint J. Stewart Brams, Registration No. 27,858, or his duly appointed associates, my agent with full power of substitution, revocation and addition, to prosecute this application and transact all business with the U.S. Patent & Trademark Office in connection therewith; and I request that all correspondence be directed to J. Stewart Brams at 300 Mt. Lebanon Boulevard, Suite 204, Pittsburgh, PA 15234.

WHEREFORE, I pray that a reissue patent be granted for the invention or discovery described and claimed in the foregoing specification and claims and I hereby subscribe my name to the foregoing specification and claims, Declaration, Power of Attorney, and this Petition.

The undersigned Petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made, are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or of any patent issuing thereon.

Date: 8/19/96

243 Ash Court

Wexford, PA 15090

Mark H. Sanders

ATTACHMENT A

4077 DIV-REISSUE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reissue Patent Application of	:	
Mark H. Sanders	:	
Serial No. (To be assigned)	:	Examiner (to be assigned)
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For Reissue of Patent 5,343,878	:	
Issued September 6, 1994	:	
For Pressure Application Method	:	

Pittsburgh, Pennsylvania

Jul 22, 1996

DECLARATION OF EUGENE N. SCARBERRY

Hon. Commissioner of Patents
and Trademarks
Washington, D. C. 20231

Sir:

I, Eugene N. Scarberry, hereby declare that:

1. I am an employee of Respironics Inc., the assignee of record in U.S. Patent 5,343,878.

2. I am making this Declaration in support of inventor Mark H. Sanders' application for reissue of patent 5,343,878.

3. I am familiar with patent 5,343,878, including the claims thereof. In particular, I am aware that all of the claims of said patent include the limitation of applying a pressure less than ambient pressure to frontal

portions of a patient's neck to distend adjacent neck tissue in a manner effective for alleviating obstruction of a patient's airway in sleep. I believe this limitation constitutes an error in patent 5,343,878 in that the inventor claimed less than he had a right to claim. The said error was discovered as follows.

4. On or about July 14, 1995, I became aware that Kingman Strohl, who is a medical consultant to Respironics Inc., had suggested the possibility that a spring biased apparatus, similar in concept to an enlarged Breathe Right (tm) brand nasal strip, could be adhesively affixed to frontal portions of a patient's neck to draw outward or distend adjacent neck tissue for the purpose of alleviating obstruction of a patient's airway in sleep.

5. Subsequently, I related Kingman Strohl's suggestion to J. Stewart Brams, the agent of record in patent 5,343,878, and inquired of Mr. Brams as to whether the patent claimed or could claim this or other alternative modalities for drawing out or distending neck tissue in a patient's neck to alleviate airway obstruction in sleep. Mr. Brams subsequently advised me that the patent does broadly disclose, and that it appeared the inventor could claim, a method including, inter alia, applying an impetus to frontal portions of a patient's neck to distend adjacent neck tissue, and that a reissue application could be filed to assert this broadened claim.

6. On may 21, 1996, I attended a meeting of the Respironics Inc. Patent Committee and related to the Committee my discussions with Mr. Brams concerning reissue of patent 5,343,878. The Committee discussed prospects for reissuing patent 5,343,878, and authorized filing of the reissue patent

application to which this declaration pertains. I then notified Mr. Brams to proceed with preparation of the proposed reissue application.

7. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application, or any patent issuing thereon.

Date:_____

_____

Eugene N. Scarberry

4077 DIV-REISSUE

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For Pressure Application Method	:	

Pittsburgh, Pennsylvania

Jul 22, 1996

DECLARATION OF J. STEWART BRAMS

Hon. Commissioner of Patents
and Trademarks
Washington, D. C. 20231

Sir:

I, J. Stewart Brams, hereby declare that:

1. I am a patent agent duly registered to practice before the United States Patent and Trademark Office under Registration No. 27,858.

2. I am making this Declaration in support of inventor Mark H. Sanders' application for reissue of U.S. patent 5,343,878.

3. I filed U. S. Patent Application Serial No. 69,739 on June 1, 1993, and prosecuted said application to issuance as Patent No. 5,343,878 on September 6, 1994. The prosecution of said application was conducted by the

assignee of record, Respironics Inc.

4. I am familiar with patent 5,343,878, including the claims thereof. In particular, I am aware that the claims of said patent are directed to a method of treating sleep apnea syndrome, and include the limitation of applying a pressure less than ambient pressure to frontal portions of a patient's neck to distend adjacent neck tissue in a manner effective for alleviating obstruction of a patient's airway in sleep. I believe these limitations constitute error in patent 5,343,878 in that the inventor claimed less than he had a right to claim. The said error occurred and was discovered as follows.

5. During the prosecution of patent 5,343,878, I did not understand or appreciate that, based on the invention as disclosed in the application, the inventor could claim a method for treating sleep apnea syndrome, or more generally a method for treating an upper airway disorder, which included, inter alia, applying to frontal portions of a patient's neck an impetus for distending adjacent neck tissue in a manner effective for alleviating obstruction of the patient's airway in sleep. I further did not appreciate that the requisite impetus could be supplied by any suitable modality not limited to pressure less than ambient pressure, and that pressure less than ambient was merely the inventor's preferred modality for supplying the requisite impetus to distend the patient's neck tissue.

6. Subsequent to July 14, 1995, Eugene N. Scarberry, an employee of the assignee, Respironics Inc., telephoned me to discuss patent 5,343,878. Mr. Scarberry related to me a suggestion by one Kingman Strohl that a spring biased apparatus, similar in concept to an enlarged Breathe Right (tm) brand

nasal strip, could be adhesively affixed to frontal portions of a patient's neck to draw outward or distend adjacent neck tissue for the purpose of alleviating obstruction of a patient's airway in sleep. Mr. Scarberry inquired as to whether patent 5,343,878 claimed or could claim this or other alternative modalities for distending a patient's neck tissue to alleviate airway obstruction. Prior to this discussion with Mr. Scarberry, I was unaware of the possibility of any such alternative modalities for applying the requisite impetus to frontal portions of a patient's neck, in accordance with the claims of patent 5,343,878.

7. On or about November 10, 1995, I undertook a review of my file of patent 5,343,878 and advised Mr. Scarberry that the patent broadly discloses, and that it appeared the inventor could claim, a method including, inter alia, applying an impetus to frontal portions of a patient's neck to distend adjacent neck tissue. During this review of my patent 5,343,878 file, I discovered a further error in said patent in that the inventive entity is misidentified on the face of the patent. I believe this further error occurred as a result of the U.S. Patent & Trademark Office having incorrectly construed papers no. 7 and 8, entered by the applicant and the examiner, respectively, during the prosecution of the patent, which papers deleted the names of inventors Scarberry and Handke, and correctly set forth that Mark H. Sanders was the sole inventor of the allowed claims.

8. Subsequent to May 21, 1996, Mr. Scarberry asked me to proceed with preparation of the proposed reissue application.

9. In conjunction with my subsequent preparation of the reissue patent application for patent 5,343,878, I concluded that the claims of the patent contained further error in that they are limited to a method of treating sleep apnea syndrome even though the pertinent disclosure in the patent is not limited to treatment of sleep apnea syndrome.

10. I advised inventor Mark H. Sanders by letter on June 21, 1996, and during a meeting with him on July 2, 1996, that the errors characterized above had been discovered in his patent 5,343,878, and that the assignee, Respironics Inc., had proposed filing of a reissue application to correct these errors.

11. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements made jeopardize the validity of the application or patent issuing thereon.

Date_____

_____

J. Stewart Brams

4077 DIV-REISSUE

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Pittsburgh, Pennsylvania

Jul 22, 1996

DECLARATION OF EUGENE N. SCARBERRY

Hon. Commissioner of Patents
and Trademarks
Washington, D. C. 20231

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application to which this declaration pertains. I then notified Mr. Brams to proceed with preparation of the proposed reissue application.

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Date: 7/29/96

Eugene N. Scarberry

4077 DIV-REISSUE

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Mark H. Sanders	:	
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Pittsburgh, Pennsylvania

Jul 22, 1996

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4. I am familiar with patent 5,343,878, including the claims thereof. In particular, I am aware that the claims of said patent are directed to a method of treating sleep apnea syndrome, and include the limitation of applying a pressure less than ambient pressure to frontal portions of a patient's neck to distend adjacent neck tissue in a manner effective for alleviating obstruction of a patient's airway in sleep. I believe these limitations constitute error in patent 5,343,878 in that the inventor claimed less than he had a right to claim. The said error occurred and was discovered as follows.

5. During the prosecution of patent 5,343,878, I did not understand or appreciate that, based on the invention as disclosed in the application, the inventor could claim a method for treating sleep apnea syndrome, or more generally a method for treating an upper airway disorder, which included, inter alia, applying to frontal portions of a patient's neck an impetus for distending adjacent neck tissue in a manner effective for alleviating obstruction of the patient's airway in sleep. I further did not appreciate that the requisite impetus could be supplied by any suitable modality not limited to pressure less than ambient pressure, and that pressure less than ambient was merely the inventor's preferred modality for supplying the requisite impetus to distend the patient's neck tissue.

6. Subsequent to July 14, 1995, Eugene N. Scarberry, an employee of the assignee, Respironics Inc., telephoned me to discuss patent 5,343,878. Mr. Scarberry related to me a suggestion by one Kingman Strohl that a spring biased apparatus, similar in concept to an enlarged Breathe Right (tm) brand

nasal strip, could be adhesively affixed to frontal portions of a patient's neck to draw outward or distend adjacent neck tissue for the purpose of alleviating obstruction of a patient's airway in sleep. Mr. Scarberry inquired as to whether patent 5,343,878 claimed or could claim this or other alternative modalities for distending a patient's neck tissue to alleviate airway obstruction. Prior to this discussion with Mr. Scarberry, I was unaware of the possibility of any such alternative modalities for applying the requisite impetus to frontal portions of a patient's neck, in accordance with the claims of patent 5,343,878.

7. On or about November 10, 1995, I undertook a review of my file of patent 5,343,878 and advised Mr. Scarberry that the patent broadly discloses, and that it appeared the inventor could claim, a method including, inter alia, applying an impetus to frontal portions of a patient's neck to distend adjacent neck tissue. During this review of my patent 5,343,878 file, I discovered a further error in said patent in that the inventive entity is misidentified on the face of the patent. I believe this further error occurred as a result of the U.S. Patent & Trademark Office having incorrectly construed papers no. 7 and 8, entered by the applicant and the examiner, respectively, during the prosecution of the patent, which papers deleted the names of inventors Scarberry and Handke, and correctly set forth that Mark H. Sanders was the sole inventor of the allowed claims.

8. Subsequent to May 21, 1996, Mr. Scarberry asked me to proceed with preparation of the proposed reissue application.

9. In conjunction with my subsequent preparation of the reissue patent application for patent 5,343,878, I concluded that the claims of the patent contained further error in that they are limited to a method of treating sleep apnea syndrome even though the pertinent disclosure in the patent is not limited to treatment of sleep apnea syndrome.

10. I advised inventor Mark H. Sanders by letter on June 21, 1996, and during a meeting with him on July 2, 1996, that the errors characterized above had been discovered in his patent 5,343,878, and that the assignee, Respironics Inc., had proposed filing of a reissue application to correct these errors.

11. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements made jeopardize the validity of the application or patent issuing thereon.

Date 8-22-96

J. Stewart Brams